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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/688,015	10/13/00	YUAN J	00742/056003

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EXAMINER	
D SOUZA,A	
ART UNIT	**PAPER NUMBER**
1626	8

DATE MAILED: 05/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/688,015	Applicant(s) YUAN ET AL.	
	Examiner Andrea M D'Souza	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *election filed May 14, 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *3-8, 11-16, 26-31, and 38-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 9, and 24* is/are rejected.

7)☒ Claim(s) *2, 10, 17-23, 25, and 32-37* is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

This action is in reply to the Applicants election of paper no. 7, dated May 14, 2001. Examiner makes note of the election of Group I, claims 1, 2, 9-10, 17-23 as amended, 24-25, and 32-37 as amended. The claims 3-8, 11-16, 26-31, and 38-40 are withdrawn from consideration as being drawn to non-elected inventions and not examined herein.

Pending Claims

Claims 1, 2, 9-10, 17-23 as amended, 24-25, and 32-37 as amended are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for neuro-degenerative diseases selected from the group consisting of Alzheimer's disease, Huntington's disease, cerebral ischemia, stroke, amyotrophic lateral sclerosis, multiple sclerosis, Lewy body disease, Menkes disease, Wilson disease, Creutzfeldt-Jakob disease, and Fahr disease, does not reasonably provide enablement for treating all conditions as identified on page 24, lines 7-12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification does not give any guidance as to how the full range conditions as identified on page 24, lines 7-12, ~~that~~ could be treated using the instant claimed process. In *In re*

Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, Applicants are claiming a method "treating a condition" using the compound as depicted in claim 24. The nature of the pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. The instant specification does not give any guidance as to how the full range of conditions as identified on page 24, lines 7-12, could be treated using the instant claimed process. In order to practice the claimed invention, one skilled in the art would have speculate which conditions as identified on page 24, lines 7-12, could be treated using the compounds found in the instant claims. The number of possible methods of treating the conditions as identified on page 24, lines 7-12, embraced by the claims would impose undue experimentation on the skilled art worker. Therefore, the broad terminology "treating a condition" is not enabled because the metes and bounds of the methods of treating conditions as

identified on page 24, lines 7-12, using the compounds found in the instant claims cannot be ascertained.

Amending the claims to insert the phrase "treating neuro-degenerative diseases selected from the group consisting of Alzheimer's disease, Huntington's disease, cerebral ischemia, stroke, amyotrophic lateral sclerosis, multiple sclerosis, Lewy body disease, Menkes disease, Wilson disease, Creutzfeldt-Jakob disease, and Fahr disease" after the phrase "a method" is suggested to obviate the above rejection.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 9, and 24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Regarding claim 1: Applicants use the phrase "A chemical compound in a pharmaceutically acceptable carrier", which renders the claim indefinite. It is unclear whether the Applicants are claiming a compound or a pharmaceutical composition. Amending the claim to claim either a compound claim or a composition claim is suggested to obviate the above rejection.

(b) Regarding claim 9: The term "contacting" in claim 9 is a relative term which renders the claim indefinite. The term "contacting" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what type of contact, i.e.

interaction the compound should have with the cell in order for the requisite end result to be achieved. Proper correction is required to obviate the above rejection.

(c) Regarding claim 24: The term "subject" in claim 24 is a relative term which renders the claim indefinite. The term "subject" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Amending the claim to specify the type of subject being treated is suggested to obviate the above rejection.

Objections

Claims 2, 10, 17-23, 25, and 32-37 are objected to as being dependent on a rejected base claim.

State of the Art

Henmi, et al and Inglis, et al are cited herein to indicate the state of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrea M. D'souza, whose telephone number is (703) 305-0811. The examiner can normally be reached on Monday-Thursday from 8:30 AM - 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Joseph.McKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1234

DEBORAH C. LAMBKIN
PRIMARY EXAMINER

Andrea M. D'souza
May 24, 2001

Deborah C. Lambkin
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